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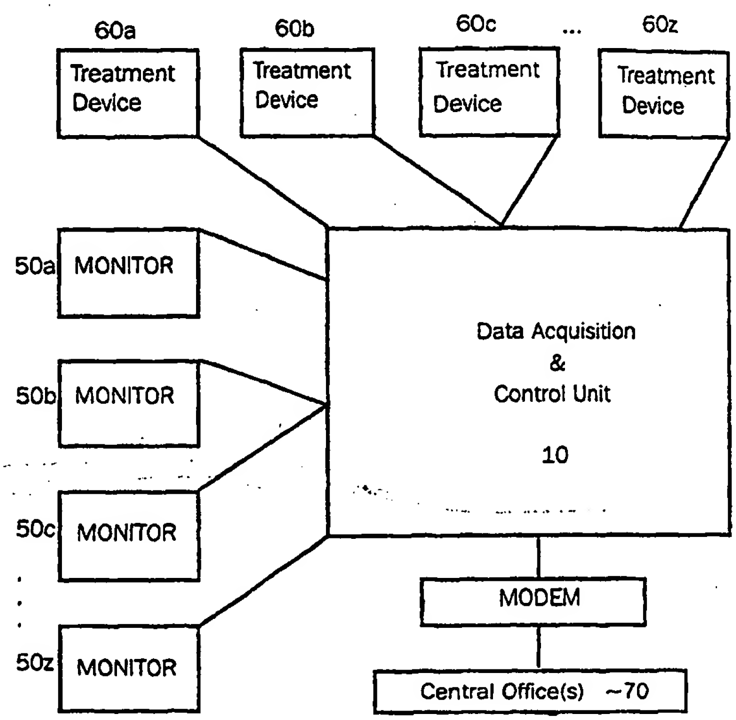
(54) Title: PATIENT DATA ACQUISITION AND CONTROL SYSTEM

(57) Abstract

The present invention solves this communication problem by providing a method and apparatus for connecting to and coordinating data communications of various medical devices having different communication protocols. In a preferred embodiment, the invention provides a way to recognize common parameters and separate out only that part of the communication that is different between and specific to the various monitors and therapeutic devices. The invention efficiently utilizes defined common parameters for protocol types and selectively configures the specific settings when required, automatically. The invention also provides the ability to connect devices having standardized communication protocols with pre-defined common communication language.



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DESCRIPTION

PATIENT DATA ACQUISITION AND CONTROL SYSTEM

Field of the Invention

This invention generally pertains to communications between medical devices and, more specifically, pertains to a method and apparatus for connecting to and coordinating data communications of various medical devices having different communication protocols.

Background of the Invention

Medical monitoring devices are used extensively in hospitals, clinics, alternative site care, *i.e.*, nursing homes, and at home to monitor a variety of medical conditions. These devices basically measure a physiologic condition/state/value from a patient and report the data representative thereof as an output of the device, typically by displaying the data on a display of the monitoring device. For example, when a measurement has been completed by a non-invasive blood pressure monitor, the systolic, diastolic, and mean blood pressure as well as the heart rate are displayed on the monitoring device. Such information could also be recorded manually by the patient or a health care provider or possibly stored in the device for future display.

Medical treatment/therapeutic devices are also used extensively in health care. These devices typically deliver a therapeutic treatment to a patient as part of the medical treatment. Examples are infusion pumps (delivering fluids and/or drugs to the patient), and ventilators (delivering gas to the patient). Each therapeutic device has a number of settings that can be modified. This is typically accomplished by various input peripherals such as buttons, knobs, key pads, and the like on the therapeutic device.

With the rapid development of computer technology, such medical devices are now mainly microprocessor-based. This technology now allows for the addition of external communications features (input/output) on the devices. At first, this communication was geared toward technicians to service the device and sometimes use the device to print out tables of data. Over the last 5 years, however, there has been a move to using this communication feature to report the output data measured by a monitor to another location (often a central office) and to remotely modify settings on a therapeutic device by communicating the appropriate input information.

A direct connection between a single device (monitor or therapeutic device) and a central station can be readily constructed. However, a problem arises in coordinating data and transmissions when multiple monitors and/or therapeutic devices are used simultaneously or interchangeably (especially if such devices were not designed to work together or come from different manufacturers). This is because medical monitoring devices and therapeutic devices differ in at least three aspects: 1) their hardware communication protocol, 2) their software communication protocol, and 3) their data (input and/or output).

In a number of industries, this problem is solved by agreeing on a set of standards to enable computers and devices to connect with one another and to exchange information with as little error as possible (i.e., standardized hardware and software communication protocols and data formats). Some of the known protocols include, for example, OSI (Open Systems Interconnection)and SNA (Systems Network Architecture). There are a multitude of standards affecting different aspects of communication, such as file transfer (XMODEM, ZMODEM), handshaking (XON/XOFF), and network transmissions (CSMA/CD).

To date, unfortunately, only a few medical devices have adapted a communication standard (*e.g.*, IEEE #P1073.1 Medical Information Bus, "MIB"). This recently introduced IEEE standard defines a set of definitions to serve as a basis for common communications among a variety of medical devices under the Medical Device Data Language (MDDL). Unfortunately, this standard was established too late in the game. Therefore, a majority of the medical devices in use today were not manufactured to meet this standard. As a result, the data that is communicated is often non-standardized, differs from manufacturer to manufacturer and even sometimes differs with various software versions of the same device. In addition, configuration data needed to start the communication process is also non-standardized.

For example, a certain hardware protocol for serial connections (e.g., RS-232, RS-422/423/449, etc.) may be defined by a number of communication parameters (e.g., baud rate, data bits, stop bits and parity). Each of the parameters have a number of settings (e.g., baud rates of 300, 600, 1200, 2400, 9600, 19200, 38400, 57600, 115200, etc.) which have not been standardized between devices. Devices also have different software communication protocols which define various formatting of data, such as if the data is designed for a line printer versus packetized data. The format is generally the structure or appearance of a unit of data. For line printers, there are parameters defining end of line characters and formats for the line. In packetized data, for example, there are parameters defining formats (packet, data), headers, and end of packet information. Again, each of these parameters include a variety of settings which are not standard in the industry. That is, none of the settings for the above-noted parameters have

been standardized. Therefore, for each device, the setting information for each parameter must be determined and configured. This process is tedious and time consuming. It requires a great deal of repetition and additional software and consumes more resources such as RAM, CPU time, coding, and the like. To avoid this problem, many choose to restrict their choice of devices to the same manufacturer where the parameter settings are hopefully the same. However, this does not provide a solution to the problem, since certain manufacturers do not sell all of the devices which may be necessary or do not provide a desired device with certain features.

Consequently, a need arises for providing a way to efficiently connect to these various devices, regardless of manufacturer and/or communication protocol parameter settings.

Brief Summary of the Invention

The present invention provides a unique method and apparatus for connecting to and coordinating data communications of various devices of differing protocols and parameter settings, whether standardized or not. In a preferred embodiment, the invention provides a way to recognize common parameters of a protocol type and separate out only that part of the communication that is different between and specific to the various monitors and therapeutic devices. The invention efficiently utilizes defined common parameters of a protocol and selectively configures the specific parameter settings when required, automatically.

Specifically, in a preferred embodiment of the invention, a method of communicating with various medical devices is provided which includes, for each connected device, identifying the common parameters for a specific protocol type and automatically configuring settings for said specific parameters. The common parameters are substantially standard between various devices having the same protocol type. For example, the common parameters for the RS-232 hardware protocol type are baud rate, data bits, stop bits, and parity. Within each of these parameters, there are specific settings which vary from device to device (e.g., baud rates of 300, 600, 1200, 2400, 9600, 19200, 38400, 57600, 115200, etc.). The specific settings for each connected device are substantially non-standard between various devices. The method also contemplates communication with medical devices which comply with industry standards (*e.g.*, MIB).

In a preferred embodiment, the specific parameter settings are automatically configured for each device by generally polling each connected device, comparing response from the polling step to a list of specific responses for each device, and setting the specific parameter settings for each device based on the comparison. This can be accomplished by sending a specific request string on a port for a device in a list of devices, and if a response to the request string is matched

identifying a specific device, configuring settings for the common parameters associated with the protocols for the device on the port, otherwise repeat sending request strings for next device in the list until a match. Preferably, a proper baud rate setting is set for the device prior to sending the request string and the steps are repeated for each port.

In an alternate embodiment, the specific parameter settings are automatically configured for each device by a) selecting a baud rate setting out of a list of standard baud rate settings, b) sending a first request string on a port, and if a first response to the first request string is matched, c) configuring settings for the common parameters associated with the protocols for a device which corresponds to the first response, otherwise repeat steps a through c for the next baud rate in the list of standard baud rates. If no responses are matched in the previous steps a through c, this embodiment may further include the steps of a) selecting a baud rate setting out of the list of standard baud rate settings, b) sending a second request string on a port, and c) if a second response to the second request string is matched, configuring settings for the common parameters associated with the protocols for a device which corresponds to the second response, otherwise repeat steps a through c herein for the next baud rate setting in the list of standard baud rate settings. Preferably, the steps are repeated for each port. If a port is specifically identified for devices communicating under a standard protocol, the settings may be pre-configured to that standard to eliminate the necessity for polling.

The present invention, in a preferred embodiment, also includes a system for communicating with various medical devices. This system includes, for each connected device, a routine for identifying the common parameters for a specific protocol type and a routine for automatically configuring settings for said specific parameters. Pre-configured ports set to certain industry standards may also be provided.

The present invention also provides a method and system for monitoring of at least one physiologic condition of at least one patient by: a) configuring a protocol of communication between at least one medical device and a data acquisition unit connected to at least one of the devices by identifying the common parameters for a specific protocol type and automatically configuring settings for said specific parameters; b) monitoring a patient's physiologic condition through at least one connected medical device to provide data representative of the physiologic condition; and c) communicating the data to the data acquisition unit connected to the device. The method may further include the step of storing the data in the data acquisition unit and transmitting the parameter to a remote location. The medical devices could include monitoring devices and/or therapeutic devices. If some form of therapeutic devices are used, or medical devices which can be adjusted with commands, the method may further include communicating

a command to control the medical device through the data acquisition unit. The communication may be initiated at a location remote from the data acquisition unit. In this method, the specific parameter settings are automatically configured for each device by polling each connected device, comparing response from the polling step to a list of specific responses for each device, and selecting the specific parameter setting for each device based on the comparison. For medical devices with standardized communication protocols, step "a" may be eliminated for known protocols.

Brief Description of the Drawings

Figure 1 is a block diagram of various monitors and therapeutic devices connected to the data acquisition and control unit of the present invention which may then be remotely connected to a central office or care center for reporting and storing data and controlling the attached devices.

Figure 2 is a schematic diagram of the circuitry of the data acquisition and control unit of the present invention.

Figure 3 is a software flow diagram of the functions and operation of the main program which generates events for data acquisition and control of the present invention.

Figures 4a, 4b, 4c, 4d, 4e, 4f, 4g, 4h, 4i, and **4j** are software flow diagrams of the functions and operation of the event system routines: initialization, exit, post, get from queue, dispatch, event generate, generate state, generate data, generate time, generate button routines respectively, of the present invention.

Figures 5a, 5b, and **5c** are software flow diagrams of the functions and operation of the device management system initialization, get device, and set device routines, respectively, of the present invention.

Figures 6a, 6b, 6c, 6d, and **6e** are software flow diagrams of the functions and operation of the device communication system initialization, get data, exit, set data, poll routines, respectively, of the present invention.

Figures 7a, 7b, 7c, and **7d** are software flow diagrams of the functions and operation of the scheduling system initialization, check, add entry, and delete entry routines, respectively, of the present invention.

Figures 8a, 8b, 8c, and **8d** are software flow diagrams of the functions and operation of the data management system initialization, get data, put data, and delete data routines, respectively, of the present invention.

Figures 9a, 9b, and **9c** are software flow diagrams of the functions and operation of the display system initialization, write, and display message routines, respectively, of the present invention.

Figures 10a, 10b, and **10c** are software flow diagrams of the functions and operation of the settings management initialization, get, and set routines, respectively, of the present invention.

Figures 11a and **11b** are software flow diagrams of the functions and operation of the input system initialization button and check button routines, respectively, of the present invention.

Figures 12a, 12b, and **12c** are software flow diagrams of the functions and operation of the external communication system initialization, send data, and receive data routines, respectively, of the present invention.

Detailed Disclosure of the Invention

Figure 1 is a block diagram of various monitors **50a, 50b, ... 50z** and therapeutic devices **60a, 60b, ... 60z** connected to the data acquisition and control unit **10** of the present invention. The unit **10** is designed to recognize, understand, and communicate with each of these devices and their unique hardware communication protocol, software communication protocol, and data requirements (input and/or output).

Initially, in formulating a solution to the communication protocol problem between various medical devices, studies were made of several physiologic monitors and therapeutic devices available in the Department of Anesthesiology at the University of Florida. The goal of this study was to determine similarities and differences between the communication of these devices. The studies showed that the low-level hardware to communicate for most of the devices was the same, and conform to the EIA RS-232 standard (EIA 1988). [EIA Standard RS-232-C 1981 Electronic Industries Association Engineering Dept. EIA Standard RS-232-C: Interface between Data Terminal Equipment and Data Communication Equipment employing Serial Binary Data Interchange. Washington DC, 1981.] However the data sent over this hardware connection and the settings and configuration of the connection are different for all monitors and therapeutic devices.

The other commonality that was discovered was the information/data sent or received over the connection. For example, a blood pressure monitor always sends systolic and diastolic blood pressure in mmHg, and a heart rate in beats/min. Based on this information, the present invention defined a common data/protocol format which would allow all of the information that

comes from the monitor and all the information that goes to a therapeutic device to be in compliance.

Generally, the present invention solved the communication problem by providing a way to separate out only that part of the communication that is different between the various monitors and therapeutic devices, and to use common methods for the rest. Communicating with devices generally requires both hardware protocols (input/output ports, serial interface, RS-232, RS-422, parallel interface, DIN, SCSI, network interface, etc.) and software/data protocols (output stream format for display or printer, character printer format, line printer format, packetized format, etc.). Each of these protocols requires a certain set of parameters to define the protocol. For example, the RS-232 hardware port has the following parameters for communication: baud rate, data bits, stop bits, and parity. Each of these parameters, in turn, have specific settings (e.g., baud rate = 300, 600, 1200, 2400, 9600, 19200, 38400, 57600, 115200, etc.) which are often unique to the device since standardized settings have not been established for all medical devices.

Although data values transmitted are often the same between similar types of devices (e.g., non-invasive blood pressure monitors generally transmit the following three data values: systolic value, diastolic value, and heart rate), the way that the data is transmitted varies from device to device. The way data is transmitted is accomplished by a certain defined protocol for communication. For example, the data can be transmitted in line printer format (protocol) or packetized format (protocol). If the protocol is of the line printer type, the parameters to define such type include the following: end of line character, format of the line. For each of these parameters, there is a particular setting such as "end of line character" = "carriage return."

The present invention provides a unique method and apparatus for connecting to and coordinating data communications of various devices having different parameter settings. As used herein, the term "protocol" generally refers to both hardware protocols and software protocols used for communication between devices, systems, and the like. The term "parameter" refers to a constant in a particular protocol which varies in other protocols of the same type used to define the particular protocol. The term "setting" refers to the value assigned to a specific parameter. The term "data" refers to the actual information transmitted (medical sensor values, etc.) as opposed to the settings information.

Table 1 below shows the relationship between the hardware communication protocol, software communication protocol, and data requirements (input and/or output) for monitors/therapeutic devices with respect to the parameters and settings.

Table 1. Monitors/Therapeutic Devices		
Aspects	Protocol	Parameter(settings)
Hardware Communication Protocol	RS232	baud rate (#)
		data bits (#)
		stop bits (#)
		parity (even, odd, none)
	Other	par-1 (#)
		par-2 (#)
		par-3 (#)
		par-n (#)
Software Communication Protocol	Line Printer	EOL (char)
		format (data)
	Packetized	packet format (type)
		header (data length)
		data (# bytes)
		EOP (CRC field)
Data Type	Type 1 - Blood Pressure	systolic BP (#)
		diastolic BP (#)
		heart rate (#)
		SpO2 (#)
	Type 2 - Infusion Pump	par-1 (#) (e.g., flow rater)
		par-2 (#)(e.g., concentration)
		par-n (#) (e.g., drug name)
	Type 3 - Other	par-1 (#)
		par-2 (#)

For example, in the case of a simple blood pressure monitor that automatically sends data each time a new measurement has been taken, the present invention uses common methods to access the RS-232 hardware, common methods to store, forward, and/or analyze the information from the monitor, and uses specific methods to interpret the data stream from the monitor.

The common identified parameters for blood pressure monitors are generally the RS-232 hardware protocol and the data transmitted with the protocol. The RS-232 protocol defines voltages and timing sequences needed to communicate data. The same set of parameters are used to fully define a connection, namely, baud rate, number of data bits, number of stop bits, and parity. Settings for these parameters are specific to a particular device, but typically the following settings are available: baud rate = 300, 600, 1200, 2400, 9600, 19200, 38400, 57600, or 115200; data bits = 7 or 8; stop bits = 0 or 1; parity = even, odd, or none. The set of data values transmitted with the protocol is also common between the same types of devices. For example, a non-invasive blood pressure monitor will usually transmit the following set of data: systolic value, diastolic value, and heart rate. These numeric values can be stored as an ASCII string or a binary representation like the IEEE float 754 specification. A timestamp can optionally be attached to the data.

The way this data is transmitted (the protocol) is different between devices (specific to the device). Two general formats are used: ASCII string terminated with a carriage return or a line feed (line printer format); or packetized protocol where binary data packets are sent back and forth. When the ASCII string format is used, the data and timestamp are also represented as ASCII. When a binary (packetized) format is used, the numeric data and timestamp data can be either ASCII or binary. When a packetized format is used, the following data items are usually present (their format depends on the device): header information (includes packet length, checksum, etc.), the data block (containing the numeric data, timestamp, units, etc.), end of packet information (usually contains a specific packet termination). Checksums are commonly calculated with the 16-bit CCITT checksum.

From the above-noted example, it can be seen that for almost any blood pressure monitor, the common parameters would be the RS-232 parameters of baud rate, number of data bits, number of stop bits, and parity (the setting for which are specific) and the set of data: systolic value, diastolic value, and heart rate (the format for which is specific). The software coding for these commonalities can be reused and only the specifics would need additional coding. Accordingly, when new blood pressure devices are added, the previously developed code for the above-identified common parameters can be re-used which saves time, resources, coding and the like.

To implement the present invention, first, a functional specification of the hardware was made. This particular implementation of the invention was designed to 1) communicate with several different physiologic monitors or therapeutic devices via a serial connection (RS-232), including sending commands to start measuring a parameter and collecting the parameters and

waveform data from the device; 2) communicate via modem(or other communication device) with a central station at certain (configurable) intervals, including accepting orders to monitor certain parameters at certain times from the central station and security -user/device identification; 3) display simple instructions to the patient; 4) accept simple input (button presses) from the patient; 5) provide an audio alarm to alert the patient to messages on the display or to indicate the next measurement is due; and 6) store data when there is no dial-up connection, even when there is a power failure.

As shown in Figure 2, the preferred embodiment of the data acquisition and control unit **10** contains the following basic hardware elements: a microprocessor **20** for control (e.g., 386 SZ 40Mhz ISA card part # PC-310-386X, available from E.G. Technology Corp., Livingston, NJ, USA); semiconductor-based memory **22** (e.g., 4Mb memory part #MM1X36-70, available from E.G. Technology Corp.); a solid-state disk drive **24** for mass storage (e.g., 1.5Mb solid-state disk for PC-310 part #OT-SSD1.5MB, available from E.G. Technology Corp.); a backplane **26** with a plurality of slots (e.g., Backplane ISA 3 slot part #BP-I3 available from E.G. Technology Corp.); a multi-port serial board **28** (e.g., four port serial board 16550 UARTS part #9013-S5-4, available from Byte Runner Technologies, Knoxville, TN, USA); and a display **30** (e.g., LCD backpack part # BPK-420L, available from Scott Edwards Electronics, Sierra Vista, AZ, USA). Additional ports, such as these for standardized Medical Information Bus communications defined by the Medical Device Data Language (MDDL-IEEE P1073), or the like may also be provided. A user interface **40** may include any standard input device(s) such as touch screen, push buttons, key board, mouse, and the like. A status light **42** may also be included. Power is preferably provided by a power source, not shown, which may be alternating or direct current (battery operated) or include battery back-up power. Standard 115 VAC power may be utilized with a power transformer **44** to provide the necessary DC output for the circuitry. A standard bus configuration **46** transmits data between the microprocessor, memory, ports and modem. If external communication is desired, a modem **48** or similar external communication device (telephone, microwave relay, satellite link, cable, network, and the like), may be provided.

The unit **10** may be directly or remotely connected to a central office **70** or care center for reporting and storing data and controlling the attached devices. In a preferred embodiment, the data acquisition and control unit **10** of the present invention preferably utilizes a single board computer capable of running the MS-DOS operating system. It is envisioned that the remote unit may be used in a variety of situations where remote monitoring may become necessary, such as on vessels out at sea, rural villages and towns, and the like. The data may be transmitted (via

modem, satellite, radio wave, wiring, infra-red, or other communication means) to a "central station" or other location as desired, such as a doctor's office, nurse's station, third-party monitoring station, alternative sites, base stations, port/naval stations (from a ship), and the like. The term "remote" as used herein does not necessarily mean "far removed." The unit **10** may be directly attached (hard-wired) to its "central office" in the same room or building. Furthermore, the functions of the "central office" (such as visual displays, data recording, control, etc.) may be incorporated into a single system in conjunction with the unit **10** if desired.

The method of the present invention in a preferred embodiment can be implemented in "C" programming language with the program running on an MS-DOS operating system. The method of the present invention is described with reference to the following description and flow diagrams of Figures 3 - 12.

The main loop of the software (Fig. 3) is operating an event system in which each task is given a finite amount of processor time. The main program **300** starts with an INITIALIZE EVENT SYSTEM **302** (the details of which are shown in Figure 4a, *evenInit* function **400**). The event system contains an event queue that allows prioritization and execution of events. The program checks for a QUIT EVENT **304** and if not posted proceeds to GENERATE EVENTS **306** and EXECUTE EVENTS **308**. This loop continues until a QUIT EVENT is posted and proceeds to DEINITIALIZE EVENT SYSTEM **310** to the end of the program **312**.

Several subsystems use the event system: the device, the scheduling system, the data management system, the display system, the settings management system, the input system, and the external communications system.

The operation of the event system is shown in the flow diagrams of Figures 4a, 4b, 4c, 4d, 4e, 4f, 4g, 4h, 4i, and 4j. The event system is initialized at the beginning of the program (Fig. 4a). The *eventInit* function **400** allocates the event queue and readies the event system for use. Deinitialization is done at the end of the program with the *eventExit* function **410** (Fig. 4b). The program can call the *eventPost* function **420** (Fig. 4c) to add an event to the queue at a certain priority. The *eventGet* function **430** (Fig. 4d) is called by the programs main loop to retrieve the next event and, when one is available, the *eventDispatch* function **440** (Fig. 4e) is called to execute the event. When no events are available, the *eventGenerate* function **450** (Fig. 4f) is called to generate any events that need to be generated, for example: GENERATE STATE EVENT **460** (Fig. 4g) which checks for message time out and whether the next scheduled event is due; GENERATE DATA EVENT **470** (Fig. 4h) which polls the DevSOMs; GENERATE

TIME EVENT **480** (Fig. 4i) which provides a timer function; or GENERATE BUTTON EVENT **490** (Fig. 4j) which checks whether a button was pushed.

The device management system is shown in Figures 5a through 5c. The device manager maintains the connection with the physiologic monitors and therapeutic devices. The *deviceManagerInit* function **500** (Fig. 5a) is called at the start of the program. The present invention defines a Device Specific Operation Module (DevSOM) for each device containing the methods that are specific to a monitor or therapeutic device and saves the various DevSOMs in a database. This database may be updated manually or automatically by remote communication as new devices are developed and/or employed. The *deviceManagerInit* function **500** makes a catalog of available device DevSOMs.

Of course, each non-standard device must be identified and configured. The present invention provides a unique automatic configuration process as described herein. The preferred method is to have a database that contains: the name of the DevSOM, the name of the device, the baud rate, a request string, a response string. This database is used to identify which devices are attached to which ports as follows: For the first device in the database, the proper baud rate is set on the first port, and the first request string is sent. A fixed time is used to wait for a response. If the response matches the response string for the first device, the device is detected. If the device was not detected, the information from the second device in the database is used, until there are no more devices. This process is repeated for all the ports. Communication with devices connected to standardized ports (*e.g.*, MIB/MDDL) may be pre-configured.

In an alternate embodiment of automatic configuration, the invention defines a database of DevSOMs that contains: the name of the DevSOM, the name of the device, response to string1 at several standard baud rates, response to string2 at several standard baud rates. This database is used to identify which devices are attached to which ports as follows: The first baud rate is selected on the first port. The first string (string1) is sent to the port. A fixed time is used to wait for a response. If the response is recognized the device is detected. If the device is not detected, a second baud rate with string1 is used. The process continues until all baud rates for string1 are tried. Then the process continues with string2. This process is repeated on the remainder of any non-standard ports. In order to rule out duplicates, it is ensured that there are no duplicate responses in the database. Other methods of polling the various ports to automatically configure the communications between the devices and the unit **10** utilizing the DevSOM database are contemplated herein.

In the preferred embodiment the DevSOMs for every device are compiled into the main program. As an alternative, the DevSOMs could be dynamically loaded from memory (or like

storage medium). When automatic configuration of DevSOMs is enabled **502**, the automatic configuration procedure, described above, is used. If automatic configuration is not enabled, a configuration file is read **502**. Running the automatic configuration identifies which device is connected to which port and which method/protocol of a specific DevSOM is to be used. For each device the *devsomInit* function contained in the DevSOM for the device is called **504**. As previously stated, only the specific methods/protocols are included in the DevSOM since commonalities have already been defined by the present invention.

The *devsomInit* function **600** of the DevSOM will do whatever initialization is needed for a specific device and will return a DevSOM data block (See Table 2) with additional information about the device. The DevSOM data block preferably contains the name of the device, the number of parameters that can be measured including their names, the number of parameters that can be modified including their names, and pointers to DevSOM functions.

Table 2. DevSOM Data Block
Name of the device
Number of measured parameters
Name list of measured parameters
Number of settable parameters
Name list of settable parameters
devsomExit function pointer
devsomGetData function pointer
devsomSetData function pointer
devsomPoll function pointer

Currently, as shown in Figures 6a through 6e, the following DevSOM functions are preferably implemented in a DevSOM: *devsomInit* **600** (Fig. 6a) - initializes the DevSOM and returns a DevSOM data block; *devsomExit* **620** (Fig. 6c)- deinitializes the DevSOM; *devsomGetData* **610** (Fig. 6b) - retrieves the latest value of a parameter, including timestamp and units; *devsomSetData* **630** (Fig. 6d) - sets a device parameter; *devsomPoll* **640** (Fig. 6d) - give the DevSOM some CPU time to do housekeeping which some devices require.

The Device Manager (Fig. 5a - 5c) is used to set and get data to/from a device. The *deviceManagerGet* function **510** (Fig. 5b) is called whenever data needs to be retrieved from a device. In this function, a specific device (as indicated by its port number) can be indicated, or the Device Manager can search the list of connected devices for a device that provides the indicated parameter.

To change data in a therapeutic device the *deviceManagerSet* function **520** (Fig. 5c) is used. It is required for this function to indicate which parameter on which device needs to be set.

Turning now to the Scheduling System (SS) of Figures 7a through 7d, this system is responsible for maintaining the schedule at which measurements are to be taken or at which treatment is to be modified. The schedule is maintained in a table which may be stored in memory such as stored on a Storage Medium (SM), e.g., solid state disk drive **24**. Each table entry contains the starting date and time of the event, the interval at which the event is to take place, the ending date and time of the event. In addition, a daily start and stop time can be indicated if, for example, measurements are only to be taken between 8:00 a.m. and 8:00 p.m.

When an event is due the event will be posted to the Event System, which implement its execution.

The SS is initialized at the start of the program with the *scheduleInit* function **700** (Fig. 7a). This function reads the schedule table from the SM. The function *scheduleCheck* **710** (Fig. 7b) is called often (as often as CPU power allows). This function checks the schedule and posts any events that are due. Entries can be added to the schedule table with the *scheduleAddEntry* function **720** (Fig. 7c), and can be deleted from the table with the *scheduleDeleteEntry* function **730** (Fig. 7d).

Turning now to the Data Management System (DMS) of Figures 8a through 8d, the DMS is responsible for storing and retrieving measured data. When data has been measured, it is passed to the DMS where it is stored in temporary storage (TS), e.g., solid state disk or RAM. Data can be retrieved from the TS and passed on to other systems via the External Communication System (FIG. 12a - 12c). After data has been forwarded to another system, data can be deleted from the TS. The TS retains its data even when the power goes out.

The DMS is initialized at the beginning of the program with the *dataInit* function **800** (Fig. 8a). This function reads the TS and creates a catalog of it in memory. The *dataPutData* function **820** (Fig. 8c) adds data to the TS and the *dataDeleteData* **830** (Fig. 8d) is used to delete data from the TS. The *dataGetData* function **810** (Fig. 8b) is used to retrieve the whole data table, or just a portion of it (for example filtered by parameter identification).

The display system (Fig. 9a - 9c) is used to display short messages to the user. The *displayInit* function **900** (Fig. 9a) initializes the Display System. Messages can either be written directly to the display with the *displayWrite* function **910** (Fig. 9b), or predefined messages can be displayed with the *displayMessage* function **920** (Fig. 9c). The *displayMessage* function **920** displays the message in the configured language and can be tailored to a specific device.

Settings Management is shown in Figures 10a through 10c. Settings can be stored and are retained even when power goes out. Settings include, but are not limited to: the number of patients using the device, their names, the phone number used by the external communication system, configured language, and the like. The *settingsInit* function **1000** (Fig. 10a) initializes the Settings Management system. Settings can be read with the *settingsGet* function **1010** (Fig. 10b) and set with the *settingsSet* function **1020** (Fig. 10c).

The Input System (Fig. 11a - 11b) provides means for the user to interact with the system. Currently, three simple input buttons are provided in the preferred embodiment. The labels for the buttons can be changed depending on the message on the display system. The activation of a button is checked with the *buttonCheck* function **1110** (Fig. 11b) which is called from the *eventGenerate* function **1100** (Fig. 11a).

The External Communication System (Fig. 12a - 12c) provides the means for transporting the data that was stored in the unit **10** to another system, or for another system to provide settings to the unit **10** or one of its attached devices. The External Communication System can communicate over standard RS-232 serial ports, modems, network adapters, or the like. Multiple connections can be maintained at the same time.

The External Communication System is initialized with the *ecsInit* function **1200** (Fig. 12a). The *ecsSendData* function **1210** (Fig. 12b) can be used to send data on the communication line and the *ecsReceiveData* function **1220** (Fig. 12c) can be used to receive data from the communication line.

Alarms can be provided for failures in the system, including an autoconfiguration failure.

Following are examples which illustrate procedures for practicing the invention. These examples should not be construed as limiting.

<u>Example 1 – Blood Pressure Monitor</u>

The *deviceManagerInit* function is called at the start of the program. The invention includes in its database a Device Specific Operation Module (DevSOM) for the particular device containing the methods that are specific to it. In this example, the invention defined the DevSOM for the "Critikon Dinamap 1846SX non-invasive blood pressure monitor with SpO2 module" by separating out the common parameters (RS-232 hardware, line printer protocol, and data set) and identifying and setting the specific protocols used in this device. The device is automatically configured according to the methods of the present invention.

In this particular example, the device utilized the common RS-232 hardware protocol. The parameters and settings for the RS-232 were defined as follows: baud rate = 600, data bits = 8, stop bits = 1 and parity = even. The *devsomInit* function opens the RS-232 port with the above settings. This function will return a DevSOM data block with additional information about the device. The *devsomExit* function is used to close the RS-232 port.

The data for such a monitor includes the following: systolic blood pressure (BPsys), diastolic blood pressure (BPdia), heart rate (HR), and SpO2. The communication protocol was defined as "line printer" for which the common parameters of end of line (EOL) character and data formats were determined to have the following specific settings: EOL = carriage return; BPsys data format = 3 ASCII characters starting at position 23 if line begins with BBC; BPdia data format = 3 ASCII characters starting at position 27 if line begins with BBC; HR data format = 3 ASCII characters starting at position 20 if line begins with BBC; SpO2 data format = 3 ASCII characters starting at position 11 if line begins with EAA. In operation, the *devsomPoll* function sends request data string1 (B*C<carriage return>) every even second and sends request data string2 (E*A<carriagereturn>) every odd second. The data is read from the device. If EOL is received, the data is parsed according to the defined data formats and stored in an internal data table ready to be retrieved by *devsomGetData* function. The *devsomSetData* function is not used with this device.

Example 2 – Multi-parameter Monitor

The *deviceManagerInit* function is called at the start of the program. The invention includes in its database a Device Specific Operation Module (DevSOM) for the particular device containing the methods that are specific to it. In this example, the invention defined the DevSOM for the "Propaq Encore multi-parameter monitor" by separating out the common parameters (hardware = RS-232, software = packetized format, and data set) and identifying and setting the specific parameters used in this device. The device is automatically configured according to the methods of the present invention.

In this particular example, the device utilized the common RS-232 hardware protocol. The parameters and settings for the RS-232 were defined as follows: baud rate = 19200, data bits = 8, stop bits = 1 and parity = even. The *devsomInit* function opens the RS-232 port with the above settings. This function will return a DevSOM data block with additional information about the device. The *devsomExit* function is used to close the RS-232 port.

The data for such a monitor includes the following: systolic blood pressure (Bpsys), diastolic blood pressure (Bpdia), heart rate (HR), SpO2 and more parameters depending on

connected inputs. The communication protocol was defined as "packet format" for which the common parameters of packet header (data length 2 bytes), data section (packet type, n bytes), end of packet information (CRC field - 2 bytes) were determined to have the specific settings as noted in parentheses.

In operation, the *devsomPoll* function sends a sensor request packet (packet type 17) for each parameter to be monitored every second. It then sends an autolink packet (packet type 5) to inform the monitor that the connection is still ongoing. It also parses the response packets and fills out an internal data table. The *devsomSetData* function is not used with this device.

Example 3 – Infusion Pump

The deviceManagerInit function is called at the start of the program. The invention includes in its database a Device Specific Operation Module (DevSOM) for the particular device containing the methods that are specific to it. In this example, the invention defined the DevSOM for the "Alaris P6000 syringe pump" by separating out the common parameters (hardware = RS-232, software = packetized format, and data set), and identifying and setting the specific parameters used in this device. The device is automatically configured according to the methods of the present invention.

In this particular example, the device utilizes the common RS-232 hardware protocol. The parameters and settings for the RS-232 were defined as follows: baud rate = 9600 baud, data bits = 8, stop bits = 1, and parity = none. The *devsomInit* function opens the RS-232 port with the above settings. This function will return a DevSOM data block with additional information about the device. The *devsomExit* function is used to close the RS-232 port.

The data for such a treatment device that can be retrieved include: total infused volume, selected drug, etc. The data for this device that can be set include: infusion rate, upper limit of the infused volume, etc.

The communication protocol was defined as "packet format", for which the common parameters of packet header (data length 3 bytes), data section (data length 2 bytes, data n bytes), end of packet information (CRC field 2 bytes) were determined to have the specific settings as noted in parentheses.

In operation, the *devSOMPoll* function sends an infused volume request packet ("0,VI ?") to request an update on the total infused volume, and a selected drug request packet ("0,DR ?") to request an update on the selected drug. The requested data is then sent back from the device, is parsed, and stored in an internal data table. The *devSOMSetData* function can be used

to update the infusion rate. The *devSOMSetData* function will send the set rate packet ("0,RS=xxx.xml/h"), which will cause the infusion rate on the pump to change as instructed.

It should be understood that the examples and embodiments described herein are for illustrative purposes only and that various modifications or changes in light thereof will be suggested to persons skilled in the art and are to be included within the spirit and purview of this application and the scope of the appended claims.

Claims

1. A method of communicating with various devices comprising identifying specific protocols for each connected device and automatically configuring settings for said common parameters associated with each of said protocols.

2. The method of claim 1 wherein said protocols comprise hardware and software protocols for communication.

3. The method of claim 2 wherein said hardware protocols comprise RS232 type comprising common parameters of baud rate, data bits, stop bits and parity associated therewith.

4. The method of claim 2 wherein said software protocols comprise

line printer type comprising common parameters of end of line character and line format, and

packetized data type comprising common parameters of packet format, header, data format, and end of packet information.

5. The method of claim 2 wherein said protocols further comprise input/output format for data sets.

6. The method of claim 1 wherein said settings are automatically configured for each device by

(a) polling each connected device,

(b) comparing response from said polling step to a list of specific responses for each device,

(c) setting said specific parameter settings for each device based upon said comparison.

7. The method of claim 1 wherein said settings are automatically configured for each device by

(a) sending a specific request string on a port for a device from a list of devices each having unique request and response strings,

(b) receiving a specific response;

(c) if said response to said request string matches, thereby identifying a device, configuring settings for said common parameters associated with said specific protocols for the device on said port, otherwise repeat steps a through c for next device in said list.

8. The method of claim 7 wherein a proper baud rate is set for said device prior to sending said request string.

9. The method of claim 8 wherein said steps are repeated for each port.

10. The method of claim 1 wherein said settings are automatically configured for each device by

(a) selecting a baud rate setting out of a list of standard baud rate settings,

(b) sending a first request string on a port,

(c) if a first response to said first request string is matched, thereby identifying a device, configuring settings for said common parameters associated with said specific protocols for the device which corresponds to said first response, otherwise repeat steps a through c for the next baud rate in said list of standard baud rates.

11. The method of claim 10 further comprising the steps of:

(a) if no responses are matched in steps a through c of method 10, selecting a baud rate setting out of said list of standard baud rate settings,

(b) sending a second request string on a port,

(c) if a second response to said second request string is matched, thereby identifying a device, configuring settings for said common parameters associated with said specific protocols for the device which corresponds to said second response, otherwise repeat steps a through c herein for the next baud rate setting in said list of standard baud rates.

12. The method of claim 10 wherein said steps are repeated for each port.

13. The method of claim 11 wherein said steps are repeated for each port.

14. A system for communicating with various devices comprising:

a routine for identifying specific protocols for each connected device and automatically configuring settings for said common parameters associated with each of said protocols.

15. The system of claim 14 wherein said selection routine performs the following steps:

(a) polling each connected device,

(b) comparing a response from said polling step to a list of specific responses for each device to identify a specific protocol for each connected device,

(c) configuring settings for said common parameters associated with said specific protocol for each device based on said comparison.

16. The system of claim 14 wherein said selection routine performs the following steps:

(a) sending a specific request string for a device in a list of devices on a port,

(b) if a response to said request string is matched, thereby identifying a device, configuring settings for said common parameters associated with said specific protocols for said device connected to said port, otherwise repeat steps a and b for next device in said list.

17. The system of claim 14 wherein said selection routine performs the following steps:

(a) selecting a baud rate setting out of a list of standard baud rate settings;

(b) sending a first request string on a port;

(c) if a first response to said first request string is matched, thereby identifying a device, configuring settings for said common parameters associated with said specific protocols for the device which corresponds to said first response, otherwise repeat steps a through c for the next baud rate in said list of standard baud rates.

18. The computer system of claim 17 further comprising the steps of:

(a) if no responses are matched in steps a through c of claim 17, selecting a baud rate out of said list of standard baud rates;

(b) sending a second request string on said port;

(c) if a second response to said second request string is matched, thereby identifying a device, configuring settings for said common parameters

associated with said specific protocols of the device which corresponds to said second response, otherwise repeat steps a through c herein for the next baud rate in said list of standard baud rates.

19. A method for monitoring of at least one physiologic condition of at least one patient comprising the steps of

(a) configuring a protocol of communication between at least one medical device and a data acquisition unit connected to at least one of said devices by identifying specific protocols for each connected device and automatically configuring settings for said common parameters associated with each of said protocols;

(b) monitoring a patient's physiologic condition through at least one connected medical device to provide data representative of said physiologic condition;

(c) communicating said data to said data acquisition unit connected to said device.

20. The method of claim 19, further comprising the step of storing said data in said data acquisition unit and transmitting said parameter to a remote location.

21. The method of claim 19, wherein at least one of said medical devices is a monitoring device.

22. The method of claim 19, wherein at least one of said medical devices is a therapeutic device.

23. The method of claim 22, further comprising the step of communicating a command to control said therapeutic device through said data acquisition unit.

24. The method of claim 23, wherein said communicating is initiated at a location remote from said data acquisition unit.

25. The method of claim 19, wherein said settings are automatically configured for each device by

(a) polling each connected device,

(b) comparing response from said polling step to a list of specific responses for each device,

(c) setting said specific parameter settings for each device based on said comparison.

26. A system for monitoring of at least one physiologic condition of at least one patient comprising:

(a) means for configuring a protocol of communication between at least one medical device and a data acquisition unit connected to at least one of said devices by identifying specific protocols for each connected device and automatically configuring settings for said common parameters associated with each of said protocols;

(b) means for monitoring a patient's physiologic condition through at least one connected medical device to provide data representative of said physiologic condition;

(c) means for communicating said data to said data acquisition unit connected to said device.

27. The system of claim 26, further comprising means for storing said data in said data acquisition unit and means for transmitting said parameter to a remote location.

28. The system of claim 26, wherein at least one of said medical devices is a monitoring device.

29. The system of claim 26, wherein at least one of said medical devices is a therapeutic device.

30. The system of claim 29, further comprising means for communicating a command to control said therapeutic device through said data acquisition unit.

31. The system of claim 30, wherein said means for communicating initiates the communication at a location remote from said data acquisition unit.

32. The system of claim 26, wherein said means for automatically configuring said specific parameter settings comprises:

(a) means for polling each connected device,

(b) means for comparing response from said polling step to a list of specific responses for each device; and

(c) means for setting said specific parameter settings for each device based on said comparison.

33. The system of claim 26 further comprising:

means for connecting standardized medical devices to said data acquisition unit wherein communication protocols are pre-defined.

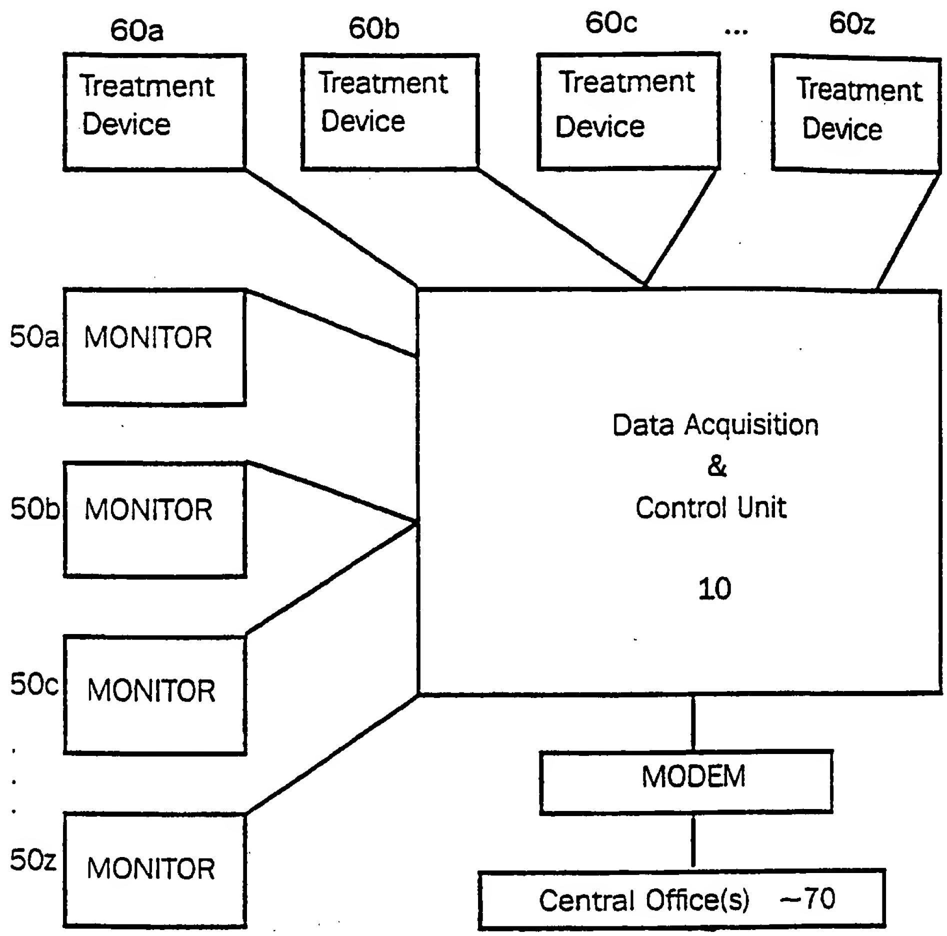
60a
60b
60c
...
60z
Treatment Device
Treatment Device
Treatment Device
Treatment Device
50a
MONITOR
50b
MONITOR
50c
MONITOR
50z
MONITOR
Data Acquisition
&
Control Unit
10
MODEM
Central Office(s) ~70

FIG. 1

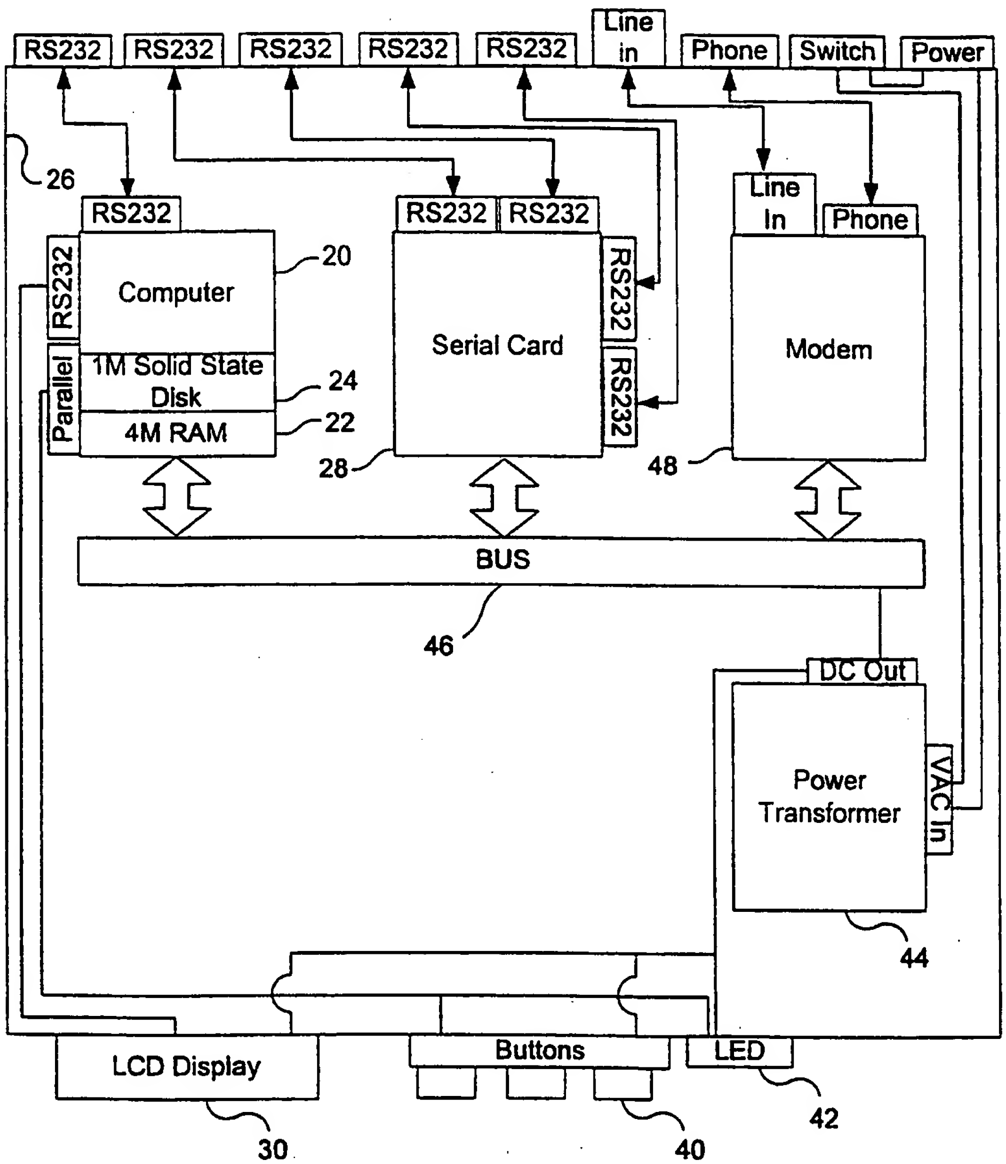
RS232
RS232
RS232
RS232
RS232
Line in
Phone
Switch
Power
26
RS232
Computer
20
RS232
1M Solid State Disk
24
4M RAM
22
Parallel
RS232
RS232
Serial Card
RS232
RS232
28
Line In
Phone
Modem
48
BUS
46
DC Out
Power Transformer
VAC In
44
LCD Display
30
Buttons
40
LED
42

FIG. 2

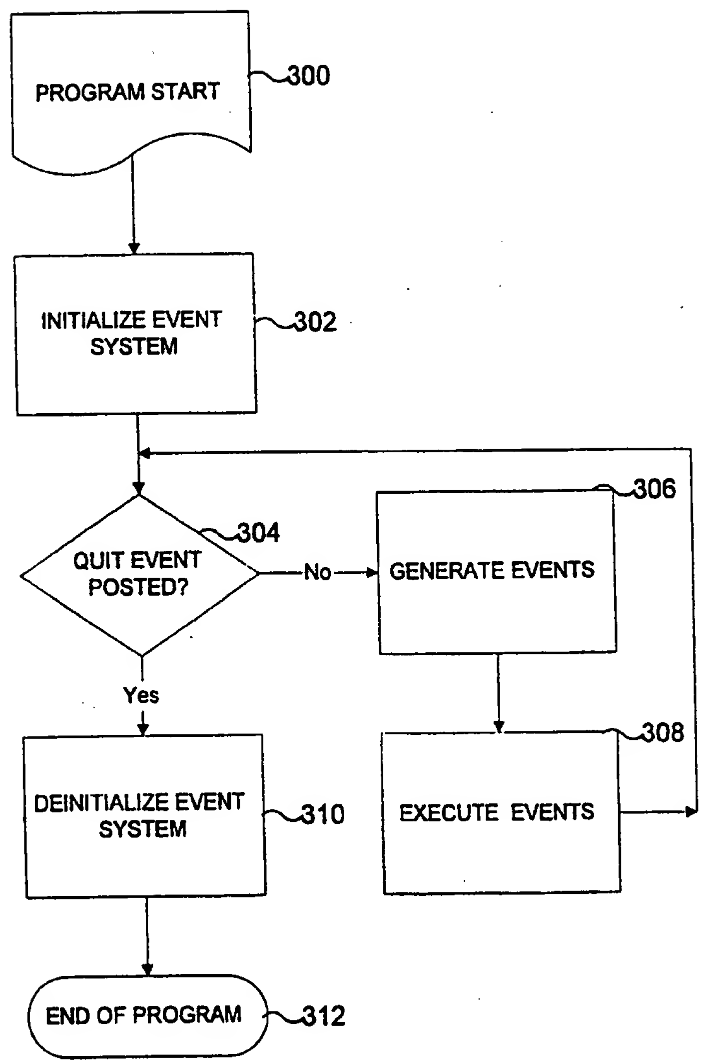
PROGRAM START
300
INITIALIZE EVENT SYSTEM
302
QUIT EVENT POSTED?
304
No
GENERATE EVENTS
306
EXECUTE EVENTS
308
Yes
DEINITIALIZE EVENT SYSTEM
310
END OF PROGRAM
312

FIG. 3

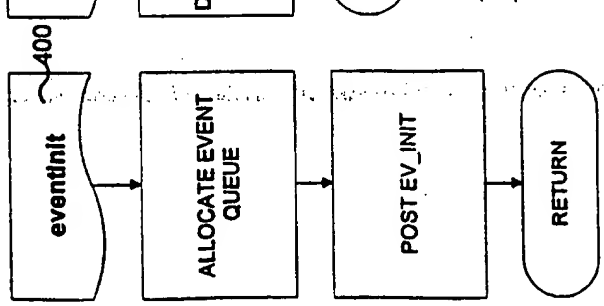

FIG. 4A

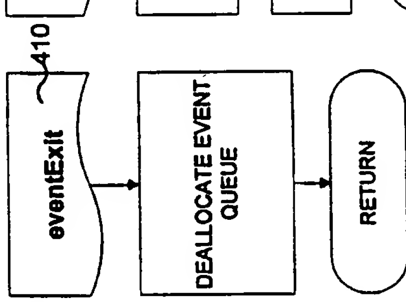

FIG. 4B

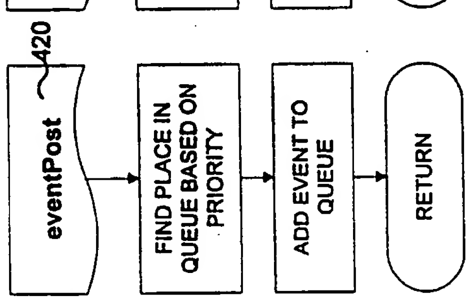

FIG. 4C

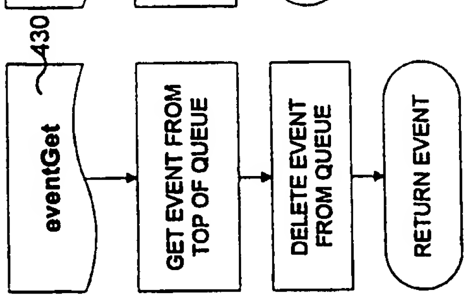

FIG. 4D

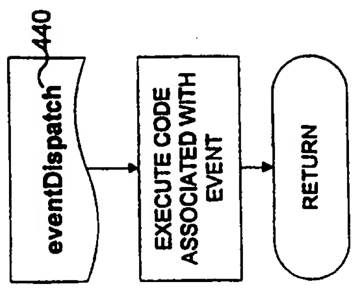

FIG. 4E

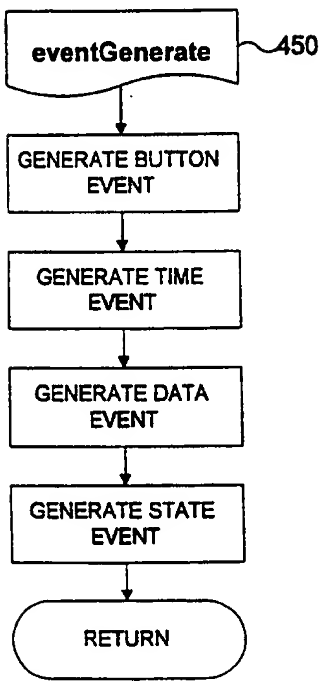

FIG. 4F

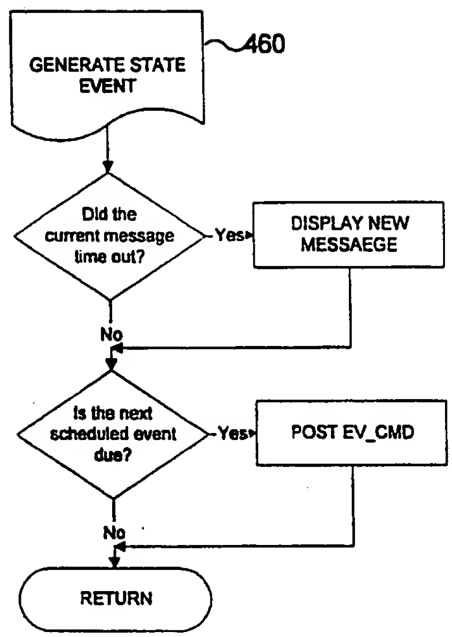

FIG. 4G

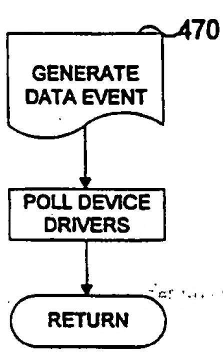

FIG. 4H

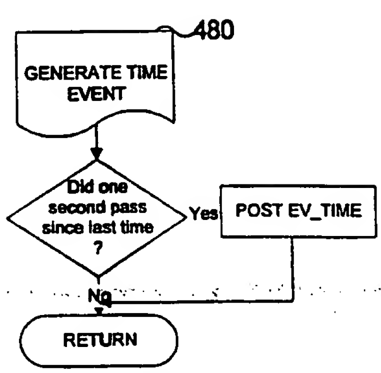

FIG. 4I

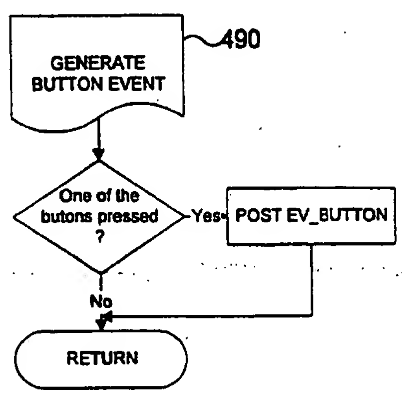

FIG. 4J

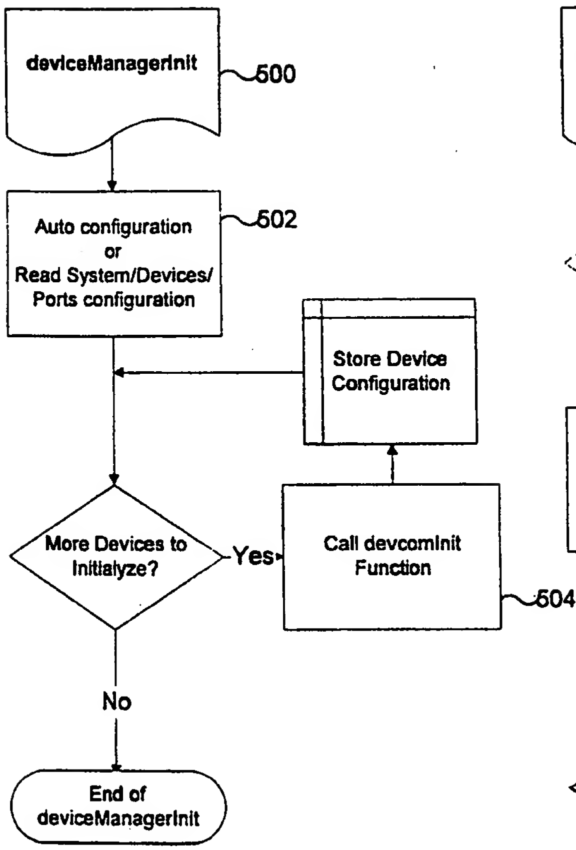
deviceManagerInit
500
Auto configuration
or
Read System/Devices/
Ports configuration
502
Store Device
Configuration
More Devices to
Initialyze?
Yes
Call devcomInit
Function
504
No
End of
deviceManagerInit

FIG. 5A

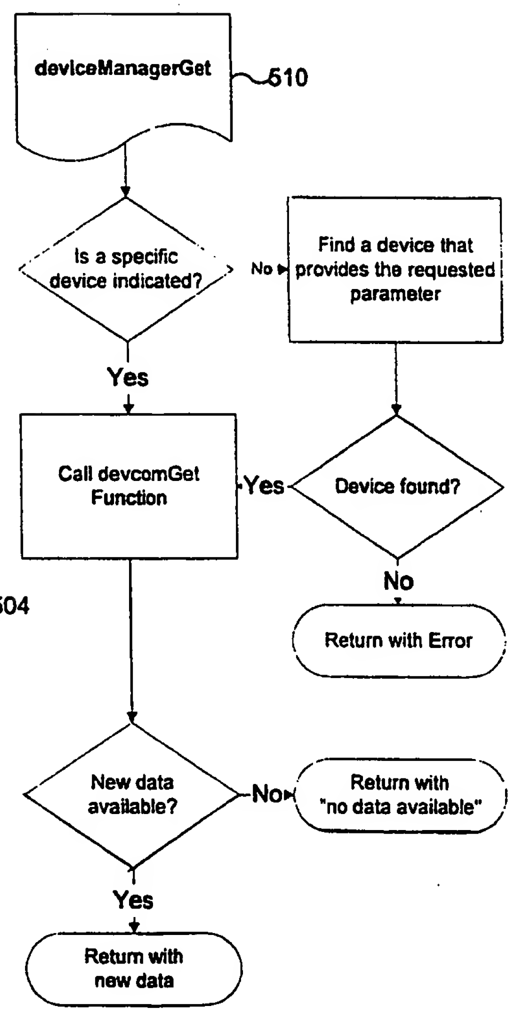
deviceManagerGet
510
Is a specific
device indicated?
No
Find a device that
provides the requested
parameter
Yes
Call devcomGet
Function
Yes
Device found?
No
Return with Error
New data
available?
No
Return with
"no data available"
Yes
Return with
new data

FIG. 5B

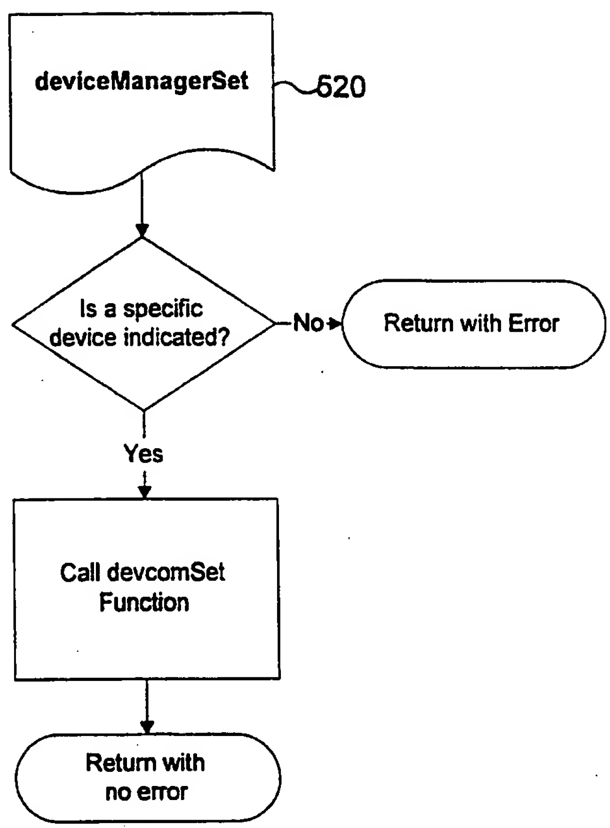
deviceManagerSet
520
Is a specific device indicated?
No
Return with Error
Yes
Call devcomSet Function
Return with no error

FIG. 5C

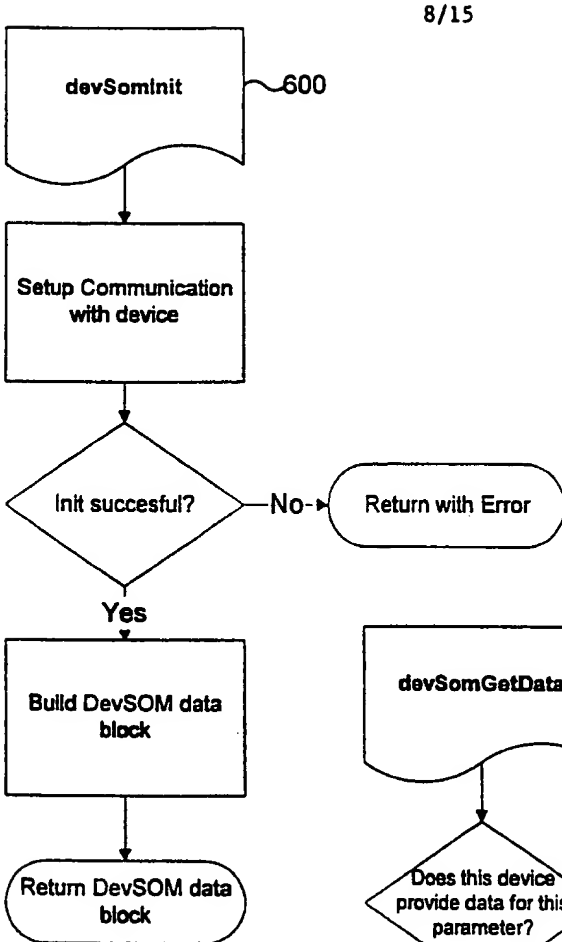

FIG. 6A

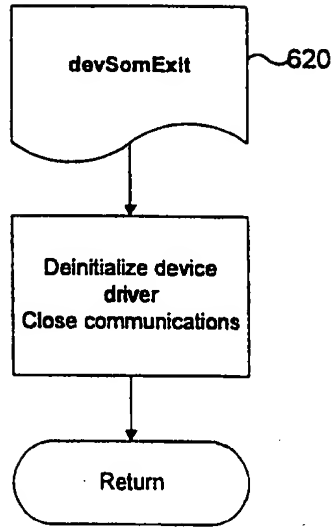

FIG. 6C

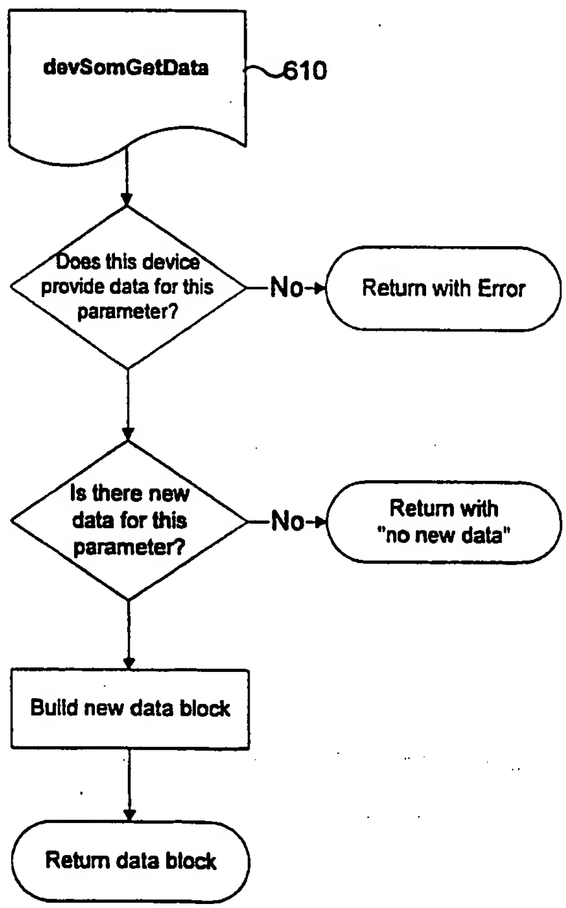

FIG. 6B

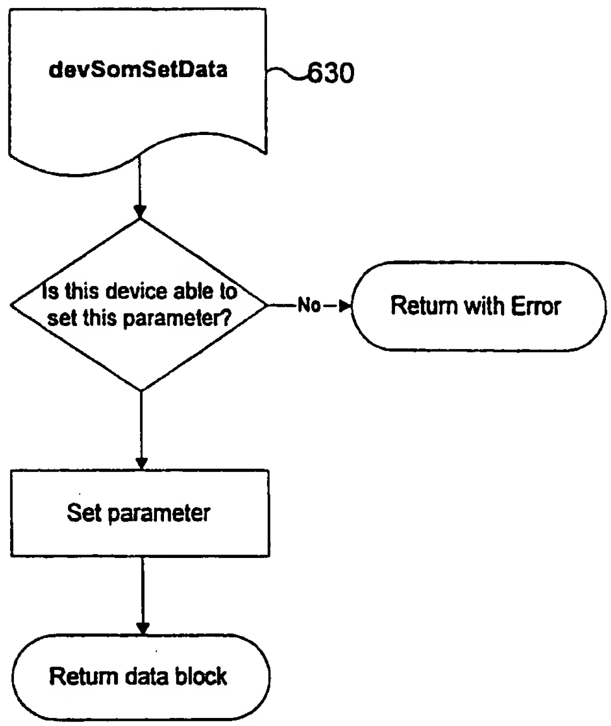
devSomSetData
630
Is this device able to set this parameter?
No
Return with Error
Set parameter
Return data block

FIG. 6D

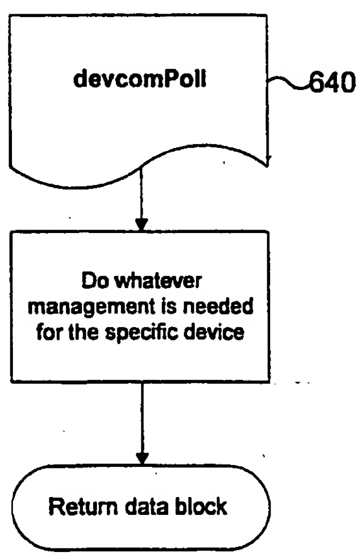
devcomPoll
640
Do whatever management is needed for the specific device
Return data block

FIG. 6E

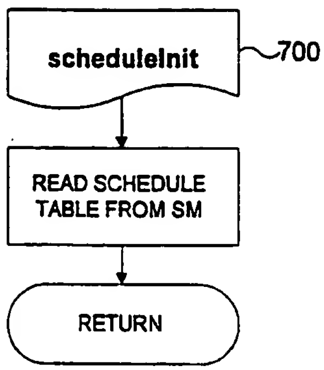

FIG. 7A

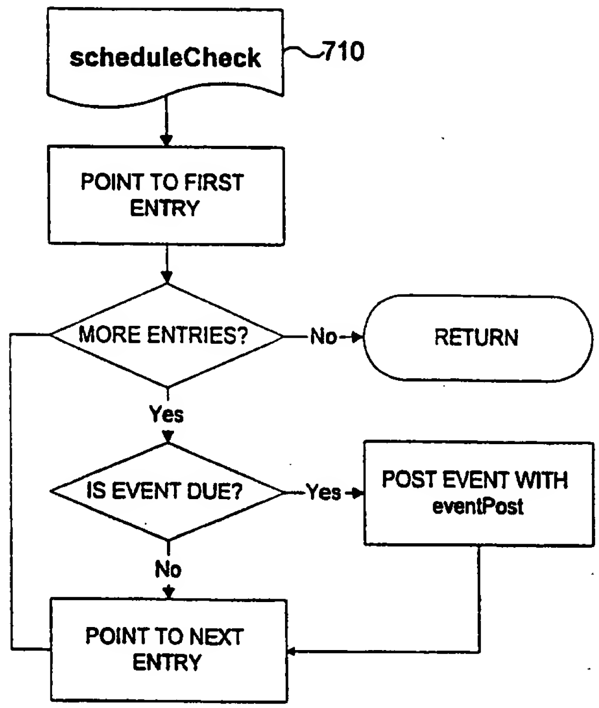

FIG. 7B

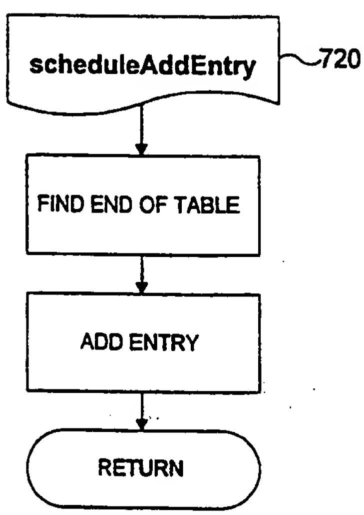

FIG. 7C

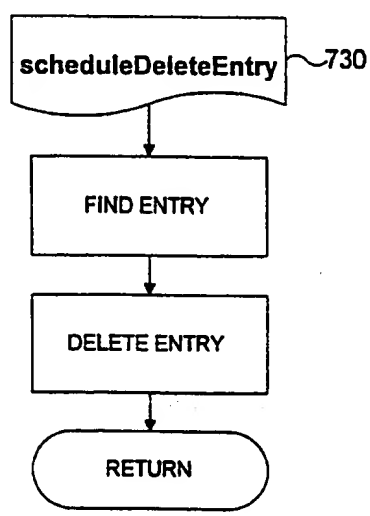

FIG. 7D

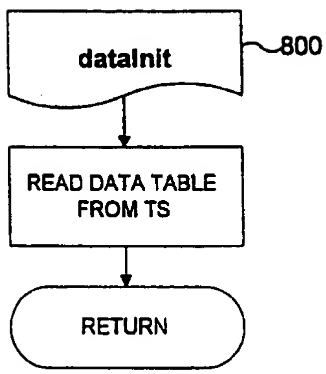

FIG. 8A

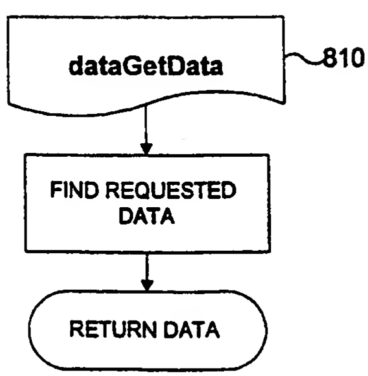

FIG. 8B

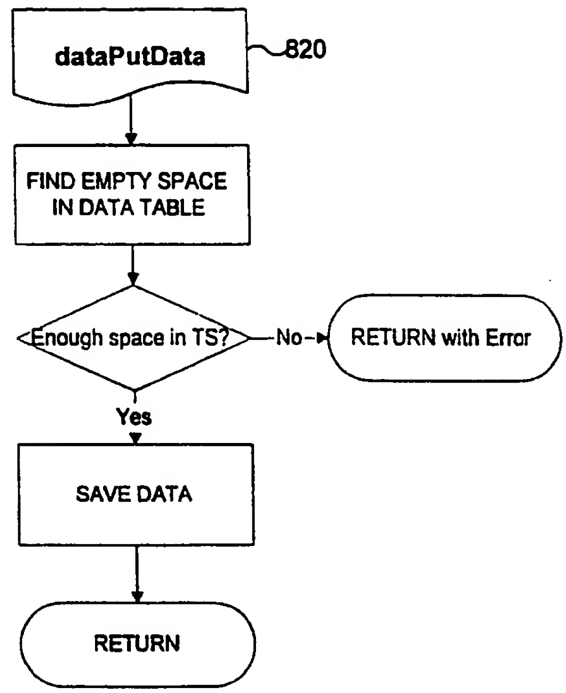

FIG. 8C

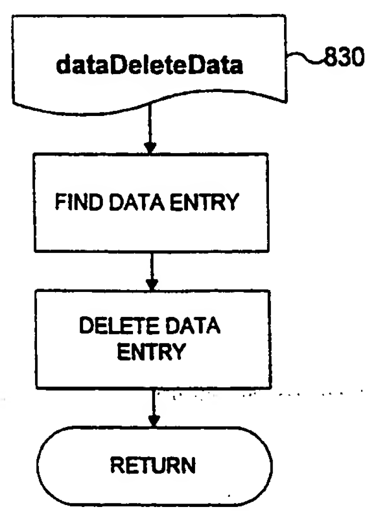

FIG. 8D

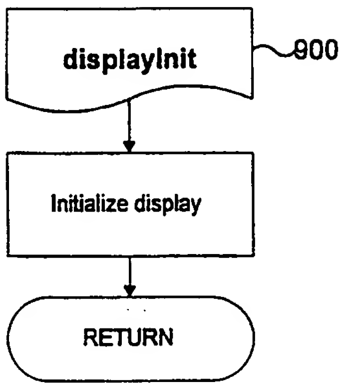

FIG. 9A

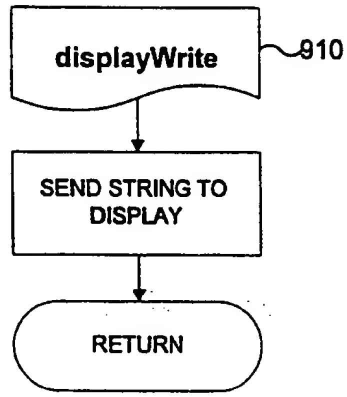

FIG. 9B

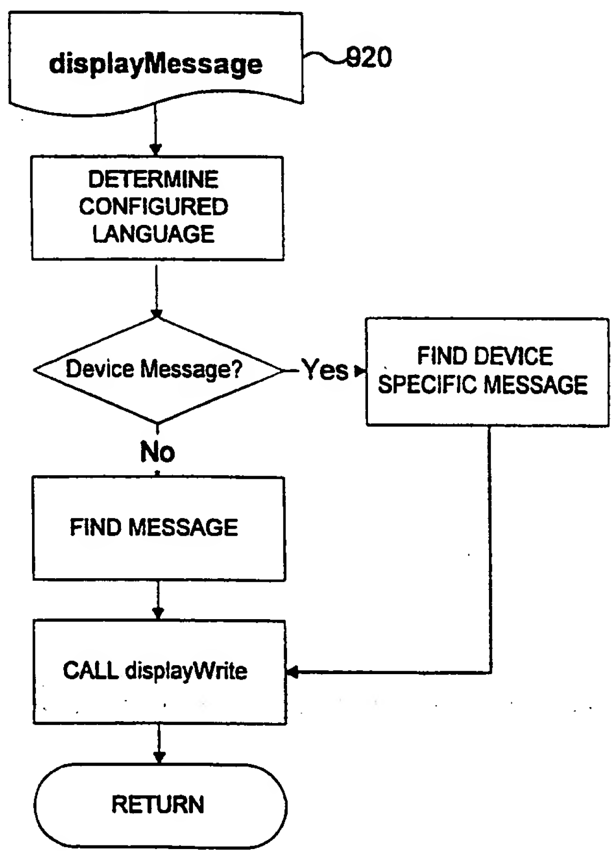

FIG. 9C

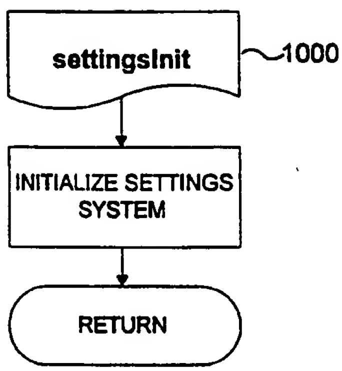

FIG. 10A

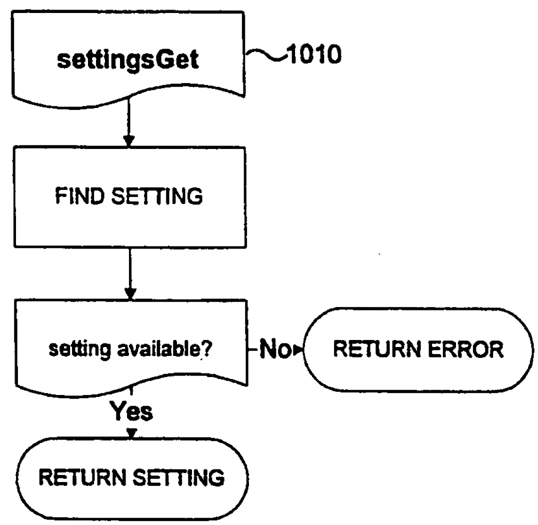

FIG. 10B

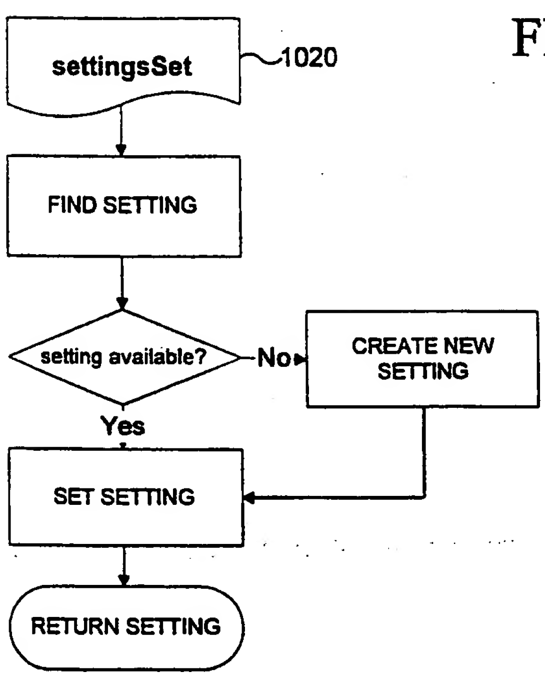

FIG. 10C

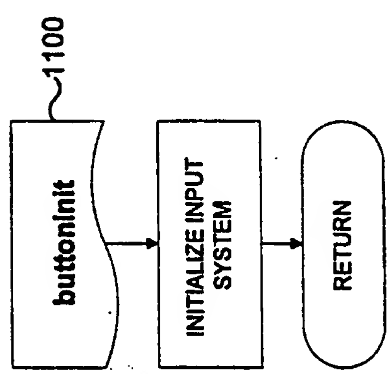

FIG. 11A

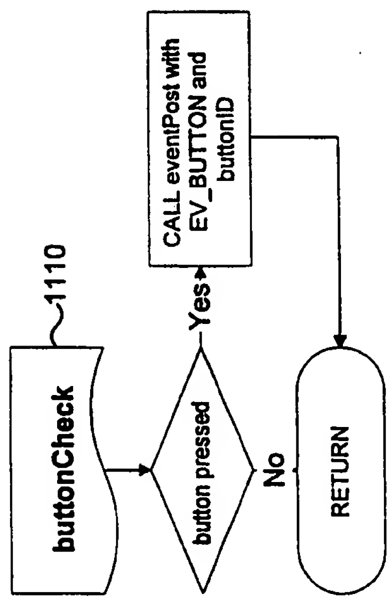

FIG. 11B

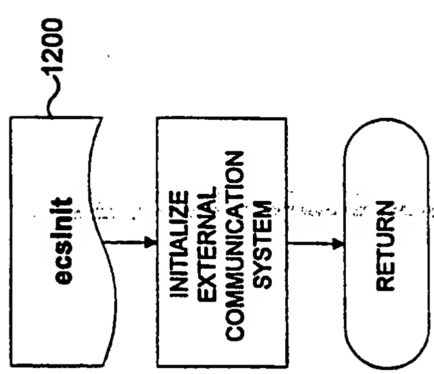

FIG. 12A

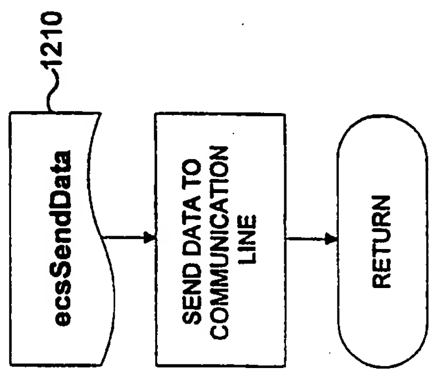

FIG. 12B

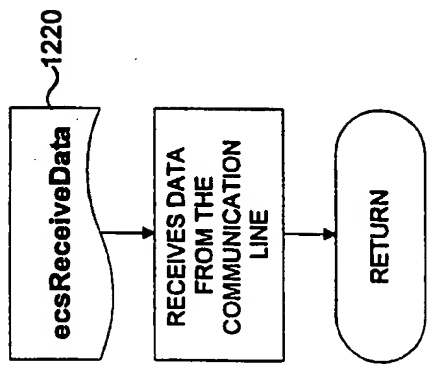

FIG. 12C

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(57) Abstract

The present invention solves this communication problem by providing a method and apparatus for connecting to and coordinating data communications of various medical devices having different communication protocols. In a preferred embodiment, the invention provides a way to recognize common parameters and separate out only that part of the communication that is different between and specific to the various monitors and therapeutic devices. The invention efficiently utilizes defined common parameters for protocol types and selectively configures the specific settings when required, automatically. The invention also provides the ability to connect devices having standardized communication protocols with pre-defined common communication language.

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INTERNATIONAL SEARCH REPORT

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Minimum documentation searched (classification system followed by classification symbols)
IPC 7 H04L

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C. DOCUMENTS CONSIDERED TO BE RELEVANT

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A		6-9, 15-18

Y	US 5 491 796 A (CHEN MICHELE ET AL) 13 February 1996 (1996-02-13) abstract column 2, line 37 - line 63 column 36, line 65 -column 37, line 58 ---	1-3,10, 14
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30 June 2000	11/07/2000

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A	US 5 416 695 A (MILLER J MARK ET AL) 16 May 1995 (1995-05-16) abstract column 2, line 3 - line 43 column 3, line 9 - line 30 column 5, line 21 - line 45	1-3,10, 14,19-33
A	EP 0 632 629 A (MULTI TECH SYSTEMS INC) 4 January 1995 (1995-01-04) abstract page 2, line 25 - line 35	1-3,10, 14

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INTERNATIONAL SEARCH REPORT

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PCT/US 99/25160

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			WO	9410625 A	11-05-1994
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